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DEPARTMENT OF HEALTH AND HUMAN SERVICE

Public Health Service

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Food and Drug Administration
New Orleans District
Southeast Region
4298 Elysian Fields Ave.
New Orleans, LA 70122

Telephone: 504-589-6341
FAX: 504-589-6360

April 30, 1999

WARNING LETTER NO. 99-NOL-26

FEDERAL EXPRESS
OVERNIGHT DELIVERY

Mr. Mark T. Abraham, President
Abe's Cajun Boudin, Inc.
120 East Napoleon Street
Sulphur, Louisiana 70663

Dear Mr. Abraham:

On February 17-18, 1999, a U.S. Food & Drug Administration (FDA) investigator conducted an inspection of your shrimp and crawfish boudin plant, located at 120 East Napoleon Street, Sulphur, Louisiana. The inspection was conducted to determine compliance with FDA's seafood processing regulations. Based on the deviations observed during this investigation, we have concluded that your shrimp and crawfish boudins are adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug and Cosmetic Act (the Act), in that they are prepared, packed and held under conditions whereby they may be rendered injurious to health in that your firm is not in compliance with the regulations of Title 21, *Code of Federal Regulations* (CFR), Part 123.

The seafood processing regulations, which became effective on December 18, 1997, require that you implement a preventive system of food safety controls known as Hazard Analysis Critical Control Point (HACCP). HACCP essentially involves: (1) identifying food safety hazards that, in the absence of controls, are reasonably likely to occur in your products; and (2) having controls at "critical control points" in the processing operation to eliminate or minimize the likelihood that the identified hazards will occur. These are the kinds of measures that prudent processors already take. HACCP provides a systematic way of taking those measures that demonstrates to us, to your customers, and to consumers, that you are routinely practicing food safety by design. Seafood processors that have been fully operating HACCP systems advise us that they benefit from it in several ways, including having a more safety oriented workforce, having less product waste, and having fewer problems generally.

During the February 1999 inspection, the FDA investigator observed shortcomings in your system that were similar to those pointed out in the July 22, 1998, inspection and stated in the untitled letter sent to your firm on August 6, 1998. The FDA investigator also provided your firm with a copy of the Domestic Seafood HACCP Report (Form FDA-3501) and the Form

FDA-483, which presents his evaluation of your firm's performance regarding various aspects of the HACCP and CGMP requirements. The form FDA-483 is enclosed for your review. The observation of concern to us is as follows:

(1) Failure to have adequate control measures for your vacuum packed products, shrimp boudin and crawfish boudin. 21 CFR Part 123.6(a) requires you to perform a hazard analysis for each seafood product that you manufacture or process. When you identify one or more food safety hazards associated with a product, 21 CFR Part 123.6(b) requires you to have and implement a HACCP plan. 21 CFR Part 123.6(c) details what a HACCP plan shall include.

We are particularly concerned with your failure to identify controls in your HACCP plan and to implement such controls to control Clostridium botulinum toxin formation in your vacuum packaged shrimp and crawfish boudin products which you store and distribute refrigerated. Unless this product is maintained in a frozen condition until immediately before use by the consumer, the only control to prevent toxin production by C. botulinum for this product is storage below 38°F, which requires constant monitoring of refrigeration during processor storage, distribution, and at the wholesale and retail level. Moreover, if the product is frozen until immediately before use by the consumer, it should be labeled as indicated on page 156 of the Hazard and Control Guide 1/98 Edition.

As the principal corporate officer, it is your responsibility to assure that your processing plant is operating in compliance with the applicable laws and regulations. It is also your responsibility to assure not only that the current objectionable conditions are corrected, but that adequate policies and procedures are implemented to prevent a recurrence of the problems.

The above identification of violations is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure adherence with each requirement of the applicable regulations. You should take prompt action to correct these deviations. Failure to promptly correct the deviations may result in regulatory action without further notice. These include seizure and/or injunction.

Your should notify this office in writing, within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of similar violations. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which corrections will be completed.

Your reply, relating to these concerns, should be addressed to the U.S. Food and Drug Administration, Attention: Carolyn S. Olsen, Compliance Officer, 4298 Elysian Fields Avenue, New Orleans, Louisiana 70122-3896. If you have any questions regarding the implementation of the HACCP regulations, you may contact Ms. Olsen at (504) 589-7166.

Sincerely,

for James E. Gamet
District Director
New Orleans District

Enclosure: FDA-483